#15 Response S. Bye 3/4/03

Attorney Docket No. MP/147

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Laguna, et al.
Appl. No. : 09/384,900
Filed : August 27, 1999
Title : An Improved Balloon Catheter And Method Of Mounting Same

I hereby certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office on February 25, 2003.

Melanee Williams

Group Art Unit: 3763
Examiner : J. Thissell

Honorable Assistant Commissioner of Patents
Washington, DC 20231

RESPONSE TO OFFICE ACTION OF AUGUST 26, 2002

Applicants respond to the Office Action of August 26, 2002, as follows.

REMARKS

In the Office Action of August 26, 2002, each of the claims of the present application was rejected under 35 U.S.C. §102(e) or §103(a) based on a newly cited reference, United States Patent 5,919,163 to Glickman (hereafter "Glickman patent"), either alone or in combination with previously cited references, or under 35 U.S.C. §102(b) based on previously cited United States Patent 5,766,201 to Ravenscroft et al. (hereafter "Ravenscroft et al. patent"). As is explained below, none of the references of record either anticipates or renders obvious the present invention as claimed. Reconsideration and allowance of the present application are respectfully requested.

The Present Invention is Both New and
Non-Obvious in Light of All the Cited References

In the present Office Action, claims 24-26, 29, 32, 37, and 40 are rejected under 35 U.S.C. §102(e) as being anticipated by the newly cited Glickman patent. Further, claims 24-30, 35-38, and 40 are rejected under 35 U.S.C. §102(b) as being anticipated by the previously cited Ravenscroft et al. patent. Claims 33, 34, 41, and 42 are rejected under 35 U.S.C. §103(a) as being obvious over the Glickman patent in view of United States Patent 5,868,704 to Campbell et

al. (hereafter "Campbell et al. patent"). Claims 28, 30,31, 36, 38, and 39 are rejected under 35 U.S.C. §103(a) as being obvious over the Glickman patent in view of United States Patent 5,843,116 to Crocker et al. (hereafter "Crocker et al. patent"). Finally, claims 27 and 35 are rejected under 35 U.S.C. §103(a) as being obvious over the Glickman patent and the Crocker et al. patent further in view of the Ravenscroft et al. patent. As is explained below, none of these rejections withstands scrutiny.

The present application includes a single independent claim, claim 24 (amended). Claim 24 (amended) specifically defines a unique structure of a sleeve that is adapted to be attached to a catheter shaft in order to create a catheter balloon. In particular, the claim reads as follows:

> 24. (amended) A sleeve adapted to be mounted on a catheter shaft so as to be formed into an inflatable balloon comprising
>
> the sleeve having a first end, a second end, and a middle section;
>
> wherein prior to mounting on catheter shaft at least one of the ends is non-distensible while the middle section of the sleeve is distensible.

As has been previously discussed, earlier inflatable balloon structures have employed tubes or wraps of material that prior to mounting on a catheter shaft are either completely non-distensible or are completely distensible. In the case of completely distensible materials, these materials were rendered non-distensible on their ends only once they were anchored to the catheter shaft through some means, such as through use of a glue, tape wrap, heat welding, etc. Prior to the present invention, no one has taught or suggested that it might be in any way beneficial to render distensible balloon material non-distensible at its ends before the material is attached to a catheter shaft.

At the interview held in the PTO on May 22, 2002, the above claim was discussed and it was contrasted with the cited Ravenscroft et al. patent and Campbell et al. patent. It was agreed that none of the references of record at that time, including the Ravenscroft et al. patent, taught or suggested the present invention as defined in claim 24 (amended). As was stated on the Interview Summary: "It was determined that Ravenscroft does not provide wrapping on the balloon before the balloon is attached to the catheter. Pending further review of Ravenscroft and other prior art, the claims appear to be allowable." Interview Summary of May 22, 2002 (emphasis in original).

The rejection based on the Ravenscroft et al. patent is maintained in the present Office Action, but no further evidence is provided to support the contention that it anticipates claim 24

(amended). In maintaining this rejection, the Office states: "Ravenscroft teaches all the claimed subject matter including a sleeve having an expandable part and a non-expandable part, due to a strip or wrapping. See col. 1, line 66 – col. 2, line 35." Office Action of August 26, 2002, at 4. Review of the Ravenscroft et al. patent reveals that a wrap is applied to a catheter shaft only after the balloon material is attached to the shaft. Ravenscroft et al. state:

> The system also includes an elastic strip attached to the catheter at opposite ends of the balloon and wrapped in a series of overlapping turns about the balloon such that the strip is elastically stretched when the balloon is expanded and elastically recovers when the expandable member is collapsed after implantation of the prosthesis.

Col. 1, lines 59 – 65 (emphasis added). It should be further noted that Ravenscroft et al. teach that the balloon itself is formed from a non-distensible material ("The balloon is formed from a nondistensible polymer" (col. 2, line 28)).

As such, the Ravenscroft et al. patent is devoid of teaching of two critical elements of the present invention as claimed. First, the balloon material itself is not in any way modified prior to attachment to a catheter shaft to render its ends non-distensible while its middle section is distensible. Second, the balloon material employed in the Ravenscroft et al. patent is entirely non-distensible, so that even following attachment to the catheter shaft the balloon material itself is non-distensible along its entire length. The Ravenscroft et al. patent simply does not anticipate claim 24 (amended) and it contains no suggestion of the present invention either alone or in combination with any of the other references of record to render claim 24 (amended) obvious.

Dependent claims 38 and 40 are also rejected as being anticipated by the Ravenscroft et al. patent. This rejection is likewise incorrect. Dependent claim 38 further defines the present invention as having at least one end that "... is covered with an essentially non-distensible material to render it non-distensible." As has been explained above, the Ravenscroft et al. patent actually teaches the precise opposite construction – a non-distensible balloon material that is covered with a strip of elastic (distensible) material. This construction is the complete inverse of that claimed in claim 38. Accordingly, if anything the Ravenscroft et al. patent directly teaches away from the claimed construction of the present invention. Similarly, dependent claim 40 defines at least one end that "...is attached to a non-distensible material to render it non-distensible." Again, the Ravenscroft et al. patent teaches a non-distensible balloon material that has an elastic (distensible) material wrapped around it, which is the opposite construction as that claimed in the present application.

Finally, dependent claims 28, 29, 36, and 37 stand rejected on the basis of the Ravenscroft et al. patent because they are allegedly "product by process claims" and therefore are not entitled to any patentable weight. Office Action of August 26, 2002, at 4. Applicants respectfully disagree that these claims define a product by process.

Dependent claims 28 and 36 define a balloon material having at least one end that "... is coated to render it non-distensible." The intent of these claims is to define a product that has an end with a coating thereon that renders the end non-distensible. These are not product by process claims, but, rather, product claims defining a balloon sleeve having a coated end. As such, the limitations defined in these claims are entitled to patentable weight. Read in this light, these claims further define the present invention over the Ravenscroft et al. patent that includes no teaching of including a non-distensible coated end on a distensible balloon sleeve.

Similarly, dependent claims 29 and 37 define an end that includes a thermal treatment to render it non-distensible. Again, these claims are intended to define products that include a thermally treated end (for instance, an end that is partially melted), which as such is non-distensible. This limitation is entitled to patentable weight and it further defines the present invention over the Ravenscroft et al. patent.

In summary, the rejection of claims 24 (amended), 25-30, 35-38, and 40 as anticipated by the Ravenscroft et al. patent is not justified. The Ravenscroft et al. patent is devoid of any teaching of multiple critical elements of the present invention as claimed. Moreover, the construction defined by the Ravenscroft et al. patent actually directly teaches away from the present invention as claimed. The rejection based on the Ravenscroft et al. patent should be withdrawn.

The newly cited Glickman patent does nothing to correct the deficiencies found in the Ravenscroft et al. patent. The Glickman patent is cited for the following proposition:

> Glickman teaches all the claimed subject matter including a piece of tubing made out of elastomeric material (col. 16, lines 43-52), which is positioned on a catheter shaft to form a balloon which is slidable along the shaft while maintaining a "fluid tight seal" (claim 8). The fact that the ends of the balloon remain tight against the catheter shaft but are moveable along it, indicates that they are non-distensible as compared to the rest of the balloon, and that the balloon is a separate piece of equipment that maintains those properties of distensibility even when not mounted on a catheter.

Office Action of August 26, 2002, at 3.

The Glickman patent teaches a double balloon catheter having a first fixed balloon and a second slidable balloon. Between the two balloons are openings for infusion and removal of targeted chemotherapeutic agents, such as toxic cancer-fighting drugs. The two balloons define a treatment zone into which the drugs are delivered. See, e.g., Abstract; col. 14, lines 25-45; col. 15, lines 9-33. Glickman teaches that it is desirable to be able to adjust the length of the treatment zone so that the physician can limit the amount and extent of exposure of toxic drugs to only specific targeted sites. Id.

In rejecting all of claims 24-26, 29, 32, 37, and 40 as being anticipated by the Glickman patent, it is asserted that the slidable balloon of the Glickman patent: (1) is constructed from elastomeric materials, (2) should have non-distensible ends when mounted tight against the catheter shaft, and (3) if removed from the catheter shaft it should have both an elastomeric center section and non-distensible ends ("...the balloon is a separate piece of equipment that maintains those properties even when not mounted on a catheter." Office Action of August 26, 2002, at 3).

The challenge with the Glickman reference is that it contains very few details concerning the slidable balloon and the nature of its attachment to the catheter shaft. Other than teaching making the two balloons from various "elastomeric materials" and adhesively bonding the balloons to the catheter shaft (col. 16, lines 43-51), the patent contains no teaching concerning how the slidable balloon is constructed from the elastomeric material or how a seal is formed at the end of the slidable balloon that can maintain a fluid-tight connection while allowing the seal to slide along the catheter shaft. However, what is taught in the patent makes it very clear that the Office's rejection is misplaced.

The Glickman patent specifically teaches that the slidable balloon must be limited in the extent of its travel along the catheter shaft. Figures 8a through 8c demonstrate that the balloon can only be moved along the catheter shaft between two "stops" provided within the balloon. The patent teaches that the two stops 180, 181 define the minimum and maximum distances between the slidable balloon and the fixed balloon. Col. 17, lines 18-34. Figure 8b demonstrates the first stop 181 within the balloon acting to prevent the slidable balloon from moving more than a maximum defined distance from the fixed balloon. Col. 17, lines 25-29. Figure 8c demonstrates the second stop 180 within the balloon acting to prevent the slidable balloon from moving any closer than a defined minimum distance from the fixed balloon. Col. 17, lines 30-34.

These first and second stops that restrict movement of the slidable balloon along the catheter shaft are critical to the Glickman patent. Each of the claims in the Glickman patent specifically defines the first and second stops being within the slidable balloon and the fact that the

stops are "constraining the sliding distance of said second [slidable] balloon" along the catheter shaft. See, e.g., Independent Claims 1, 7, and 10.

In light of this teaching, it is plain that the slidable balloon of the Glickman patent in no way anticipates the present invention as claimed. As has been discussed at length, the present invention calls for a balloon sleeve "... having a first end, a second end, and a middle section; wherein prior to mounting on catheter shaft at least one of the ends is non-distensible while the middle section of the sleeve is distensible." In rejecting this claim, the Office asserts that Glickman's slidable balloon can be separated from its catheter shaft in order to meet each of the limitations claimed in the present application ("the balloon is a separate piece of equipment that maintains those properties of distensibility even when not mounted on a catheter."). This argument is baseless since the presence of the critical stops within the Glickman balloon makes it impossible to remove the Glickman slidable balloon from the catheter shaft without destroying the catheter and perhaps the balloon in the process. Moreover, even if the catheter shaft were destroyed to remove the Glickman slidable balloon assembly, it still fails to meet the limitations of the present invention as claimed since the properties of the present invention need to be present "prior to mounting on the catheter shaft."

On the other hand, although Glickman does not teach how his slidable balloon assembly is initially placed on either side of the stops on the catheter shaft, it must be assumed that the slidable balloon is assembled in situ around the catheter shaft with each of its ends anchored to slidable seals formed on either side of the first and second stops. There is no teaching or suggestion within the Glickman patent of any other method of manufacture. Constructed in this manner, again the Glickman patent is devoid of any teaching or suggestion of a distensible balloon sleeve that has non-distensible ends prior to attachment to a catheter shaft. In this respect, the Glickman patent is similar to the numerous other prior art patents that take a distensible balloon material and render its ends non-distensible once the material is attached to a catheter shaft. As was discussed and acknowledged at the interview on May 22, 2002, the present invention as claimed clearly defines over such a construction.

Accordingly, the Glickman patent neither teaches nor suggests the present invention as claimed in independent claim 24 (amended). Additionally, none of dependent claims 25, 26, 29, 32, 37, or 40 is anticipated by the Glickman patent. Claims 25 and 26 define structure that is formed when the balloon sleeve with non-distensible ends defined by claim 24 (amended) is subsequently mounted on a catheter shaft. The Glickman patent does not anticipate or suggest such a construction. Similarly, claims 29, 32, 37, and 40 each define structures that render the

end of the balloon sleeve non-distensible prior to mounting on the catheter shaft. Again, the Glickman patent contains no teaching of rendering the ends of a distensible balloon sleeve non-distensible prior to mounting on a catheter shaft, much less any suggestion of particular structures to accomplish such a goal. Finally, as was noted in the previous discussion with respect to the Ravenscroft et al. patent, claims 29 and 37 define a structure and not a product by process and therefore are entitled to patentable weight. For the foregoing reasons, the rejection of claims 24 (amended), 25, 26, 29, 32, 27, and 40 based on the Glickman patent should be withdrawn.

Claims 33, 34, 41, and 42 have been rejected as being obvious over the Glickman patent in view of the Campbell et al. patent. For the reasons set forth above, the Glickman patent does not teach critical claimed elements of the present invention. The Campbell et al. patent does nothing to remedy the deficiencies of the Glickman patent. As was discussed and acknowledged at the interview on May 22, 2002, the Campbell et al. patent does not teach or suggest modifying the ends of a distensible balloon material to render them non-distensible prior to mounting on a catheter shaft. Accordingly, this rejection should likewise be withdrawn.

Claims 28, 30, 31, 36, 38, and 39 have been rejected as being obvious over the Glickman patent in view of the Crocker et al. patent. Once again, the Glickman patent does not teach critical claimed elements of the present invention. The Crocker et al. patent is directed at providing "expansion-limiting bands" along the length of an expandable balloon to create a balloon that has different "zones" of expansion along its length. The Crocker et al. patent neither teaches nor suggests that a balloon material should be rendered completely non-distensible at its ends prior to mounting on a catheter shaft. Accordingly, combined the Glickman and Crocker et al. patents contain no teaching or suggestion of the present invention as claimed.

Finally, claims 27 and 35 have been rejected as being obvious over the Glickman and Crocker et al. patents in further view of the Ravenscroft et al. patent. In this regard, it is asserted that the Ravenscroft et al. patent suggests wrapping the ends of a balloon sleeve to make then non-distensible. As has been previously noted, the Ravenscroft et al. patent teaches wrapping a catheter shaft with an elastomeric (distensible) tape that is then wrapped around a non-distensible balloon material. This patent neither teaches nor suggests the present invention as claimed and it does not overcome any of the deficiencies of the other references of record.

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Conclusion

For the foregoing reasons, the present invention as defined by claims 24 (amended) and 25 through 42 is neither taught nor suggested by any of the references of record. Reconsideration and allowance of the amended claims are respectfully requested. If any questions remain, applicants request an interview prior to the next Office Action.

Respectfully submitted,

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